

# NAVY AND MARINE CORPS PUBLIC HEALTH CENTER

ENVIRONMENTAL PROGRAMS DEPARTMENT



**What You Don't Know About Your Human Health Risk Assessment Could Hurt You (...and Your Site Decisions)**

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7 May 2009

*“Protecting Health and the Environment”*

<b>Report Documentation Page</b>			<i>Form Approved OMB No. 0704-0188</i>					
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1. REPORT DATE <b>07 MAY 2009</b>	2. REPORT TYPE	3. DATES COVERED <b>00-00-2009 to 00-00-2009</b>						
<p>4. TITLE AND SUBTITLE <b>What You Don't Know About Your Human Health Risk Assessment Could Hurt You (...and Your Site Decisions)</b></p>			5a. CONTRACT NUMBER					
			5b. GRANT NUMBER					
			5c. PROGRAM ELEMENT NUMBER					
<p>6. AUTHOR(S)</p>			5d. PROJECT NUMBER					
			5e. TASK NUMBER					
			5f. WORK UNIT NUMBER					
<p>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) <b>Navy and Marine Corps Public Health Center, 620 John Paul Jones Circle, Suite 1100, Portsmouth, VA, 23708</b></p>			8. PERFORMING ORGANIZATION REPORT NUMBER					
<p>9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)</p>			10. SPONSOR/MONITOR'S ACRONYM(S)					
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)					
<p>12. DISTRIBUTION/AVAILABILITY STATEMENT <b>Approved for public release; distribution unlimited</b></p>								
<p>13. SUPPLEMENTARY NOTES <b>Presented at the NDIA Environment, Energy Security &amp; Sustainability (E2S2) Symposium &amp; Exhibition held 4-7 May 2009 in Denver, CO.</b></p>								
<p>14. ABSTRACT</p>								
<p>15. SUBJECT TERMS</p>								
<p>16. SECURITY CLASSIFICATION OF:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33.33%; padding: 2px;">a. REPORT <b>unclassified</b></td> <td style="width: 33.33%; padding: 2px;">b. ABSTRACT <b>unclassified</b></td> <td style="width: 33.33%; padding: 2px;">c. THIS PAGE <b>unclassified</b></td> </tr> </table>			a. REPORT <b>unclassified</b>	b. ABSTRACT <b>unclassified</b>	c. THIS PAGE <b>unclassified</b>	<p>17. LIMITATION OF ABSTRACT <b>Same as Report (SAR)</b></p>	<p>18. NUMBER OF PAGES <b>21</b></p>	<p>19a. NAME OF RESPONSIBLE PERSON</p>
a. REPORT <b>unclassified</b>	b. ABSTRACT <b>unclassified</b>	c. THIS PAGE <b>unclassified</b>						

# Presentation Overview

- What is Human Health Risk Assessment (HHRA)?
- Risk Assessment vs. Risk Management
- Effective Use of HHRA
  - Data Evaluation
  - Exposure Assessment
  - Toxicity Assessment
  - Risk Characterization
- Navy and Marine Corps HHRA Support



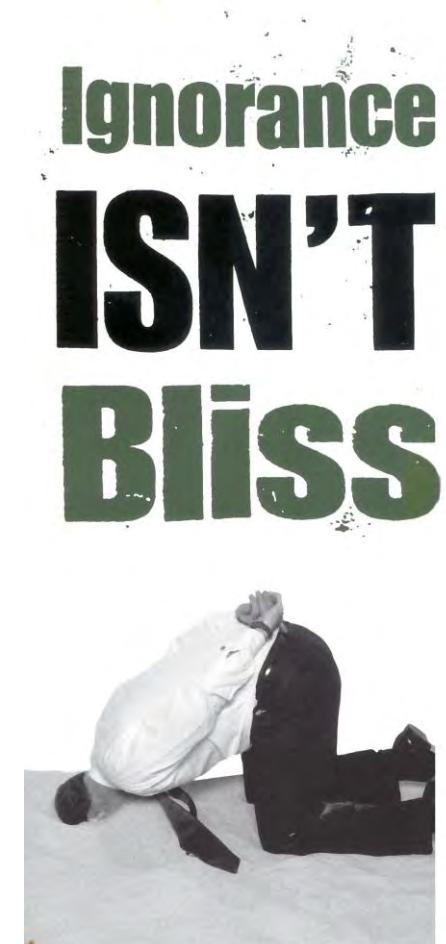
# What is HHRA?

- Read all about it!
  - Review key guidance documents
    - Navy guidance and policy
      - <http://www-nehc.med.navy.mil/hhra/process/index.htm>
      - <http://www-nehc.med.navy.mil/hhra/guidancedocuments/policy/pdf/hrapolicy.pdf>
    - EPA's —Risk Assessment for Superfund" series
      - <http://www.epa.gov/ower/riskassessment/ragsa/index.htm>
  - CECOS course on —Human Health Risk Assessment"
    - <https://www.netc.navy.mil/centers/csfe/cecos/>
  - Call me...I can talk about this for hours!



# Why Bother with HHRA?

- Key component of CERCLA investigations
- Goals of Superfund HHRAs:
  - Provide an analysis of baseline risks
  - Determine need for remedial action
  - Determine levels of chemicals that can remain on site and still be protective
  - Compare health impacts of various remedial alternatives
  - Consistent process for evaluating and documenting possible health effects



# Risk Assessment vs. Risk Management

- Risk Assessment
  - Performed by risk assessor
    - Input from other technical areas
  - Based on best-available science
  - Integrated throughout entire investigation
    - Scoping, PA, SI, RI, FS, etc.
  - Formal analysis and written report/documentation
- Risk Management
  - Performed by RPM, regulators, etc.
    - Input from risk assessor
  - Based on stakeholder comfort levels with risk, uncertainty, etc.
  - At the end of each stage of the investigation
  - Usually informal; not always documented

# Risk Assessment vs. Risk Management



No...not this either!

# Effective Use of HHRA: Data Analysis

- Does the sampling strategy support the HHRA?
  - Sampling supports other aspects of the site investigation (e.g., ecological risk assessment, nature and extents, remedial design, etc.), which may have different needs than the HHRA
    - Lateral and vertical extent given the exposure areas and receptors
    - Sample collection techniques
    - Analytical methods and detection limits
  - Combining datasets (temporally and spatially)
  - Upfront and continual involvement of risk assessor

# Does the sampling strategy support the HHRA? (con't)

- Why this matters
  - The data is the foundation for the entire HHRA! If the data isn't appropriate for the HHRA, run into the —garbage in—garbage out” phenomenon!
- Prevention
  - Upfront and continual involvement of risk assessor

# Effective Use of HHRA: Data Analysis

- How are background conditions being assessed?
  - Baseline HHRA evaluates incremental risks from exposure to site-related contamination
  - Comparison of site conditions to background
    - Navy Policy on the Use of Background Chemical Levels (2004)
    - [http://web.ead.anl.gov/ecorisk/policy/pdf/Final\\_Navy\\_Background\\_Policy.pdf](http://web.ead.anl.gov/ecorisk/policy/pdf/Final_Navy_Background_Policy.pdf)
  - Upfront and continual involvement of risk assessor, chemist, geologist, statistician, etc. (in other words, whatever it takes!)

# How are background conditions being assessed? (con't)

- Why this matters
  - If background isn't separate, the cleanup goals may be below background conditions!
- Prevention
  - Upfront and continual involvement of risk assessor, chemist, geologist, statistician, etc. (in other words, whatever it takes!)

# Effective Use of HHRA: Exposure Assessment

- Is residential land use reasonably expected at the site?
  - Conservative exposure scenario
  - Navy policy
    - “Do not evaluate unrealistic exposure scenarios that are not likely to take place at the site.”
  - EPA guidance
    - HHRA and FS should focus on the development of practicable and cost-effective remedial alternatives, leading to site activities that are consistent with the reasonably-anticipated future land use.

# Is residential land use reasonably expected at the site? (con't)

- Why this matters
  - This assumption could lead to overly conservative and costly remedial goals
- Prevention
  - Support your risk assessor by doing homework about local land use
  - Initiate this dialog early and often with regulators

# Effective Use of HHRA: Exposure Assessment

- Does the HHRA evaluate both the reasonable maximum exposure (RME) and central tendency exposure (CTE) scenarios?
  - Consistent with Navy policy and EPA guidance
  - RME is conservative and thus generally considered protective

# Does the HHRA evaluate both RME and CTE scenarios? (con't)

- Why this matters
  - HHRA is not an “exact” science and thus a single number (hazard index or cancer risk) for a single exposure scenario does not necessarily result in practicable, cost-effective site decisions
- Prevention
  - Discuss both scenarios and how they will be used in decision making with regulators

# Effective Use of HHRA: Toxicity Assessment

- Are cleanup decisions being made for chemicals that have Tier 3 toxicity values?
  - EPA hierarchy of sources for toxicity values and Tier 3 is appropriate, but has the lowest confidence
    - Tier 3 sources are more uncertain
    - Subject to more frequent update (read: CHANGE)
    - Many Tier 3 sources, so possibly many Tier 3 toxicity values (and thus opinions on those values)

# Are cleanup decisions being made for chemicals that have Tier 3 toxicity values?

- Why this matters
  - Any remedial decisions made on chemicals with Tier 3 toxicity values may be subject to dispute/change more often than other sources
- Prevention
  - Educate regulators
  - May want to accept a higher —acceptable risk” level based on uncertainty surrounding the toxicity value

# Effective Use of HHRA: Risk Characterization

- Have the risk managers considered the uncertainty assessment or are they just focused on the numerical output?
  - The risk characterization *serves as the bridge between risk assessment and risk management and is therefore a key step in the ultimate site decision-making process*” (EPA, 1989).

# Effective Use of HHRA: Risk Characterization

- Numerical outputs are not the only (or most important) part of the risk characterization
  - Quantitative estimates of risk (i.e., calculation of incremental lifetime cancer risks and hazard indices [HIs] for non-carcinogens),
  - Qualitative descriptors of risk
  - Uncertainty assessment, and
  - Summary of the risk characterization results.
- Numerical outputs are conditional estimates based on many assumptions

# Navy and Marine Corps HHRA Support

- Navy and Marine Corps Public Health Center
  - HHRA professionals available for FREE consultation or review of RI-related documents
  - Technical review is advantageous because NMCPHC offers an unbiased set of eyes that may identify issues with the HHRA such as:
    - Development of appropriate DQOs;
    - Identification of COPCs;
    - Identification of data gaps;
    - Use of appropriate analytical method/detection limit;
    - Appropriate handling of analytical results near the limits of detection;
    - Identification and use of appropriate toxicity values;
    - Evaluation of appropriate potentially complete exposure pathways; and
    - Clarification of risk characterization to facilitate decision-making.

# For Additional Information

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# Questions?

